REMARKS

Regarding the Final Office Action of 5/17/2005, Claims 1-26 remain pending in the application and stand rejected. Applicant respectfully requests that claims 1, 8, 17 and 18 be amended as indicated above, and that the following remarks be considered.

Further, Applicant and inventor, Dr. Michael Rutter, submits herewith a Declaration under 37 CFR §1.132. The Declaration elucidates how Dr. Rutter, being one of ordinary skill in the art, decided upon the ratios between the distal, intermediate and proximal portions of the tube of the present invention, and provides evidence of the criticality of these ratios for the proper function of the invention, which is not taught, suggested, or motivated in the cited references.

Applicant asserts that the claims as amended comply with 37 C.F.R. §1.116 such that they are fully supported in the application as originally filed and contain no new matter, and respectfully request reconsideration for the following reasons.

I. Claim Rejections under 35 USC §102(b) – rejection of Claims 1, 3-11, 15, and 17

Claims 1, 3-11, 15, and 17 remain rejected under 35 USC §102(b) as anticipated by Beck, Jr. et al., US Patent No. 5,339,809 ("Beck"). Examiner asserts that Beck discloses a short distal section of tubing similar to Applicant's. Examiner also asserts that Beck discloses an elongated proximal section of tubing similar to Applicant's. Further, Examiner asserts that the Applicant fails to describe "how short/elongated", or "short/elongated to what," such that the terms "short" and "elongated" "are considered broad terms in which the Beck reference reads on."

Regarding the distal section of the tube disclosed by Beck in comparison to Applicant's tube, Applicant believes that the Examiner's assertion is incorrect, since Beck describes its distal section as "elongated" (see Beck Claim 1: "a first elongated and hollow tube portion"). Thus, Beck discloses an elongated distal section, or elongated "end tube section 2" (see Beck FIG. 1), in direct contrast to Applicant's short distal section.

Regarding the proximal section of the tube disclosed by Beck in comparison to Applicant's tube, Applicant believes that the Examiner's assertion that Beck discloses an elongated proximal section similar to Applicant's is also incorrect. FIG. 2 of Beck illustrates that Beck's proximal tube section 12 is shorter than the other sections of the tube. Thus, Beck discloses a short proximal section, in direct contrast to Applicant's elongated proximal section.

Regarding how short or elongated the various sections of tubing are, Applicant has amended independent Claims 1 and 17 in order to better define the terms "short" and "elongated" as they apply to the distal and proximal sections of the tube, respectively. Specifically, the phrase "wherein the ratio of the length of the distal section to the length of the intermediate section is from about 1.0 to about 2.0, and the ratio of the length of the proximal section to the length of the distal section is from about 2.0 to about 4.0" has been added to independent Claims 1 and 17. That is, referring to these ratios, the elongated proximal section must be between about 2 to about 4 times longer than the short distal section, and the short distal section must be between about equal to and about twice the length of the intermediate section. Thus, the distal section of the Applicant's tube, besides being termed "short," now also has required parameters within which it must fit in order to be considered "short." Likewise the proximal section of the Applicant's tube also has required parameters within which it must fit in order to be considered "elongated." Dependent claims 8 and 18 have also been amended to include further limitations of these claimed ratios.

Since amended Claims 1 and 17, as well as their depending claims including Claims 3-11 and 15, now include a definitive comparison between the short distal, intermediate, and elongated proximal sections, the Applicant asserts that the terms "short" and "elongated" are sufficiently described and limited such that they can no longer be considered broad terms that the Beck reference reads on. The distal and proximal sections of the Beck tube do not fit the ratios of the distal and proximal sections of the tube claimed by the Applicant.

In summary, to anticipate a claim, the cited reference must disclose each limitation of the claim at issue. Beck does not disclose all of the limitations of independent claims 1 and 17, as currently amended. Rather, the opposite is true, since the distal end tube section 2 of Beck is elongated where Applicant's is short, and the proximal tube section 12 of Beck is short where Applicant's is elongated. Similarly, these limitations are also attributed to dependent claims 3-11, and 15, and are similarly not disclosed by Beck. As such, Beck does not disclose each limitation of Claims 1, 3-11, 15, and 17.

II. Claim Rejections under 35 USC §103(a) – rejection of Claims 2, 12, 18-20, 23-25

Claims 2, 12, 18, 19, 20, 23, 24, and 25 remain rejected under 35 USC §103(a) as allegedly being unpatentable over Beck, Jr. et al., US Patent No. 5,339,809 ("Beck") in view of Nye, US Patent No. 5,590,647 ("Nye"). The Examiner asserts that Nye clearly states that at least one portion of its tube be made of a flexible material, not ruling out that the entire tube be made of a flexible material.

Applicant respectfully disagrees, and asserts that there is no such flexible portion as that of Nye in the tube of the present invention. The term "flexible" as intended by Nye is different than the term "flexible" as intended by the Applicant. The term "flexible" as used by Nye refers to a portion of the tube that "enables greater access to the head and neck of a patient during surgery, **wherein the proximal end of the tracheal tube is capable of being shifted or moved during use**" (see Nye at Column 3, Lines 23-26, emphasis added). More specifically, Nye discloses a "tracheal tube which includes a segment of flexible tubing on the proximal end, **the flexible tubing allowing for full 360° rotation** of the proximal end relative to the distal end of the tracheal tube" (see Nye at Column 6, Lines 56-59, emphasis added).

In contrast, Applicants tube is not able to be shifted or moved during use, and in no way can Applicants tube allow for full 360° rotation, because it has no such material that is capable of being moved like this. Rather, Applicants tube is made of a material that returns to its original shape no matter how much one tries to shift or move it.

Claim 1 of Nye recites "a distal end portion; ...a flexible intermediate portion; ...and a proximal portion." (Emphasis added). Indeed, the flexible portion intended by Nye is the "flexible intermediate portion" of the tube, which is **more flexible than** the distal or proximal ends. The more flexible material of Nye is needed to solve the perceived problems associated with having a tube that returns to its pre-formed shape following flexure. This flexible tube portion is further described in Nye at Column 6, Lines 18-24:

> Flexible portion 30, or 130, may be formed of any suitable flexible material which **allows for acute bends** while maintaining constant connection to the other portions of the tracheal tube 10, or 100. **This material must be capable of such bends without kinking** or transferring unnecessary force to the proximal end portion 40, or the distal end portion 20, **while maintaining constant inside and outside diameters.** (Emphsis added)

Further, Nye teaches away from a tube made entirely of a thermoplastic material preformed to the shape described, by pointing out that preformed tubes have disadvantages that Nye's intermediate flexible portion overcomes. See Nye at Column 2, Line 61 – Column 3, Line 13:

> **[T]he curve of the preformed tubes must be controlled accurately to correspond with the anatomy of the patient.** While standard sizes and shapes will be appropriate for most patients, there are many occasions when the predetermined curve will leave the proximal extension at an improper distance from the facial region. This may result in excessive pressure being exerted on sensitive tissue in the nasal and oral regions, as well as to the mucosa and trachea at the distal end of the tracheal tube. [...] Also, the preformed tracheal tubes do not allow for shifting of the tube during an operation, but rather may be positioned in only one way. (Emphasis added)

The present invention seeks to provide a tube which does exactly what Nye is trying to avoid, a tube that corresponds with the anatomy of the patient. There is no room in the tube of the present invention to have a flexible portion that can bend 360° in any direction, since the tube of the present invention seeks to fit perfectly with the anatomy of the patient. The disclosure of specific ratios for the proximal, intermediate and distal portions of Applicant's tube serve to verify that the tube is meant to correspond with the anatomy of the patient. Indeed, while Nye's solution is to provide a flexible portion that "allows easy relocation of the proximal end of the tube without requiring disconnection of the anesthesia circuit," and allows "the tube to be easily moved and located in an infinite number of positions," (see Nye at Column 3, lines 33-40), the present invention's solution is to provide an elongated proximal portion intended to allow the anesthesia circuit to be connected away from the head and neck during surgery.

The flexibility feature of the tube disclosed by Nye is not a result of the entire tube being in a preformed shape, as is claimed in Claims 2, 12, 18-20 and 23-25 of the present invention. Rather, Applicant asserts that Nye's tube has a flexible portion that does not return to its preformed shape and which is not part of the present invention, and that Nye teaches away from a tube that is entirely made of a material preformed to the shape described. To articulate a *prima facie* case of obviousness, the art cited against the pending claims must teach all the limitations of the rejected claims. Claims 2, 12, 18 and 23 recite: "wherein all sections and bends of the

flexible tube are made of a thermoplastic material preformed to the shape described." In light of the above, Applicant contends that not all of the limitations of the claims have been met by the above-cited references, neither individually or in combination, since Nye teaches away from having the entire tube made of a thermoplastic material preformed to the shape described. Therefore, the rejection fails to articulate a *prima facie* case of obviousness. Applicant therefore respectfully requests the rejection be withdrawn and Claims 2, 12, 18, 19, 20, 23, 24, and 25, as amended, be duly allowed.

III. Claim Rejections Under 35 USC §103(a) – rejection of Claims 13, 14, 16, 21, and 22

Claims 13, 14, 16, 21, and 22 remain rejected under 35 USC §103(a) as being unpatentable over Beck, Jr. et al., US Patent No. 5,339,809 ("Beck") in view of Joseph, US Patent No. 5,582,167 ("Joseph").

Examiner asserts that Beck discloses the invention with the exception of providing a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate, and that Joseph teaches a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate. Applicant respectfully disagrees.

First, in light of the current amendments to independent claims 1 and 17, above, Applicant asserts that Beck does not disclose the present invention as claimed, even in view of Joseph. Second, Applicant asserts that even if for the sake of argument Beck is still considered to disclose the present invention, Joseph does not teach a tracheostomy tube that provides a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate.

While FIG. 1 of Joseph illustrates an endotracheal tube with what the Examiner construes as an alleged eye or port adjacent to a beveled terminal end, the "port" depicted in FIG. 1 of Joseph is not labeled in the Figure, is not discussed in the Specification, and is not mentioned in the claims. Rather, Joseph is concerned more about disclosing an irrigation channel that delivers liquids such as saline or antibiotic and antifungal medications for mucosal hydration, and bactericidal action against infected subglottic secretions. An outer sleeve surrounding the endotracheal tube forms a suction lumen for removing the secretions. Electronic and mechanical

dependent claims 8, 18 and 26, include ratios relating to the relative lengths of the various sections of the tube.

Specifically, Dr. Rutter used typical anatomical measurements seen by him in his extensive clinical practice to create these claimed ratios. These ratios are thus not a matter of design choice, but are necessary to function as Dr. Rutter intended.

Typical distances exist (for both adults and children) for the following anatomical reference points: the distance from stoma site in the trachea to the carina (covered by the distal section of the tube); the distance from the inner trachea to the chest wall (covered by the intermediate section of the tube); and the distance from the stoma site at the chest wall to the oxygen source (covered by the proximal section of the tube). Dr. Rutter notes that typically a 2 year-old patient requiring a tracheostomy has a distance of between about 6 cm to about 8 cm from the stoma site in the trachea to the carina (the carina being the bifurcation point of the trachea into the bronchial tree), a distance of between about 4 cm to about 6 cm from the inner trachea to the chest wall, and a distance of between about 20 cm to about 24 cm from the chest wall to the oxygen source (which would be positioned away from the patient during surgery, as explained below).

Similarly, in an 8 year-old patient, there is a distance of between about 8 cm to about 10 cm from the stoma site in the trachea to the carina, a distance of between about 5 cm to about 8 cm from the inner trachea to the chest wall, and a distance of between about 24 cm to about 28 cm from the chest wall to the oxygen source. Furhter, in a typical adult patient (male or female), there is a distance of between about 10 cm to about 12 cm from the stoma site in the trachea to the carina, a distance of between about 6 cm to about 10 cm from the inner trachea to the chest wall, and a distance of between about 30 cm to about 35 cm from the chest wall to the oxygen source.

With all of these distances provided in the attached Declaration by Dr. Rutter, which he states are important to the determination of the claimed ratios and thus to the proper use and function of his claimed tube, there is a common thread wherein the ratio of the length of the distal section to the length of the intermediate section is from about 1.0 to about 2.0, and the ratio of the length of the proximal section to the length of the distal section is from about 2.0 to about

4.0. This last phrase is thus included in currently amended claims independent claims 1 and 17, and is also present in independent claim 23. Further, as claimed in dependent claims 8 and 18 (currently amended), and dependent claim 26, these claimed ratios can be further limited such that the ratio of the length of the distal section to the length of the intermediate section is from about 1.2 to about 1.8, and the ratio of the length of the proximal section to the length of the distal section is from about 2.5 to about 3.5.

If the claimed ratios are not used then there is an increased likelihood for untoward events to occur. For example, the short distal section is necessarily short to avoid endobronchial intubation, and the intermediate section is necessarily short to precisely fit the length of the stoma site between the chest wall and the esophagus. Since the intermediate section is needed to cover the distance between the trachea and the chest wall, which is a short distance in the average human, this section is the shortest section of tubing. The claimed ratios reflect this fact. Further, the distal section is also short, typically about the same length as, or slightly longer than, the intermediate section, since the distal section of the tube must be shorter than the distance between the stoma and the bronchi to prevent endobronchial intubation. The disclosed ratios reflect this as well.

Regarding the proximal section, it is important during surgery for the anesthesiologist to have access to the patient's airway. If the surgeon is operating in the mouth or upper airway, then the anesthesiologist is relegated to place the anesthesia machine in an area of the operating room that is located an uncomfortable distance away from the patient's upper airway. Typically this position is away from the patient's head, either at the foot of the bed or one side of the bed away from the head of the bed. Thus, if the proximal section of the tracheostomy tube is elongated, as is claimed in the present application, then the anesthesiologist can easily access the connection at the end of the proximal section of the tube to the anesthesia machine, which carries oxygen to the patient. Therefore the proximal section of tubing is necessarily elongated in order to allow the anesthesiologist access to the end of the tube and to keep this access location away from the body cavity of the patient during use (See page 2, para. 32 of the published application). For this reason, the proximal section generally is at least twice as long as the distal section, and typically is about three times as long as the distal section (page 2, para. 34).

The published application notes that the tracheotomy endotracheal tube of the invention is useful for individuals of all ages. (See page 2, para. 28 of the published application) "The length of the distal, intermediate, and proximal sections will vary depending on the size of the tracheotomy endotracheal tube, e.g., whether it is intended for use on an adult or a child." (Page 2, para. 34 of the published application). Further, the claimed bends 16, 20 in the tube of the present invention mark the transitions between the sections (distal, intermediate and proximal) of tubing, and dictate the disclosed ratios. These bends 16, 20 correspond to specific parts of the human anatomy, with pre-formed bend 16 conforming to the bend created at the transition between the tracheotomy stoma and the trachea (see page 2, para. 30 of published application), and bend 20 conforming to the bend created at the transition between the stoma and the chest wall of a patient (see page 2, para. 31).

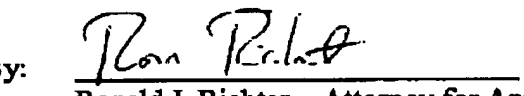
While the differences in the actual size between the pediatric and adult airways can be significant, the overall three-dimensional proportions in upper airway size between adult, pediatric, male and female airways are basically the same. Because the average human being falls within a predictable range of sizes and proportions, the tube of the present invention can be manufactured within the claimed ratios in order to fit all sizes of individuals.

As a result of the foregoing argument, all of the claimed ratios have criticality in the design and function of the tube, so that it can be useful for individuals of all ages. The ratios disclosed in Claims 1, 8, 17, 18, 23 and 26 correspond to these functional features of the tube, and are not a result of simple design choice. Therefore, Applicant respectfully requests that this rejection be withdrawn and the claims be allowed.

CONCLUSION

Applicants believe that each point raised in the Final Office Action dated 5/17/2005 has been addressed in the present Amendment. Therefore, Applicants respectfully request continued examination and consideration of this application in view of the attached Declaration and the foregoing remarks and amendments, and that all the instant claims be duly allowed. The Examiner is invited to contact the undersigned directly with any questions or remaining issues regarding the pending claims.

Respectfully submitted,
For MICHAEL J. RUTTER

By: 

Ronald J. Richter – Attorney for Applicant
Reg. No. 52,408
Customer No. 38155
(513) 229-0383 – phone
(513) 229-0683 – fax

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